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NOTICE OF ALLOWANCE AND FEE(S) DUE

22204 7590 09/09/2009 NIXON PEABODY, LLP

401 9TH STREET, NW SUITE 900 WASHINGTON DC 20004-2128 EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645 DATE MAILED: 09/09/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|-------------|----------------------|---------------------|------------------|--|
| 10/809,831 | 03/26/2004 | Thomas R. Kozel | 031673-003000 | 7955 | |

TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR DETECTION, PREVENTION, AND TREATMENT OF ANTHRAX AND OTHER INFECTIOUS DISEASES

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | YES | \$755 | \$300 | \$0 | \$1055 | 12/09/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT, PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

| appropriate. All further indicated unless corrects maintenance fee notifica | correspondence includir ed below or directed oth | of transmitting the 1336 g the Patent, advance of herwise in Block 1, by (a | rders and notification of r a) specifying a new corres | naintenance fees wi pondence address; | ill be and/or | mailed to the current (b) indicating a sepa | correspond trate "FEE | fence address as ADDRESS" for |
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| 22204 | 7590 09/09 | /2009 | nave | | | of Mailing or Trans | mission | |
| NIXON PEAB 401 9TH STREE SUITE 900 | ET, NW | | I he Stat addi tran | cobsequentify that this | Confe | s) Transmittal is being ficient postage for first ISSUE FEE address I) 273-2885, on the d | r denocited | with the United l in an envelope being facsimile d below. |
| WASHINGTON | N, DC 20004-2128 | | | | | | | (Depositor's name) |
| | | | | | | | | (Signature) |
| | | | | | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | | ATTO | RNEY DOCKET NO. | CONFIRM | MATION NO. |
| 10/809,831 | 03/26/2004 | | Thomas R. Kozel | | 031673-003000 | | | 7955 |
| TITLE OF INVENTION INFECTIOUS DISEASE | | ED METHODS FOR DE | TECTION, PREVENTIO | N, AND TREATM | ENT (| OF ANTHRAX AND | OTHER | |
| APPLN, TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE | FEE | TOTAL FEE(S) DUE | D. | ATE DUE |
| nonprovisional | YES | \$755 | \$300 | \$0 | | \$1055 | 12 | 2/09/2009 |
| EXAM | IINER | ART UNIT | CLASS-SUBCLASS | | | | | |
| SWARTZ, I | RODNEY P | 1645 | 435-007100 | • | | | | |
| | ondence address (or Cha B/122) attached. ication (or "Fee Address 12 or more recent) attach | nge of Correspondence | 2. For printing on the p (I) the names of up to or agents OR, alternativ (2) the name of a singl registered attorney or s 2 registered patent atto listed, no name will be | 3 registered patent rely, e firm (having as a igent) and the name meys or agents. If n | attorn memb s of u | era 2 | | |
| PLEASE NOTE: Uni recordation as set fort (A) NAME OF ASSI | less an assignee is ident h in 37 CFR 3.11. Comp GNEE | | THE PATENT (print or typ data will appear on the p T a substitute for filing an (B) RESIDENCE: (CITY inted on the patent): | atent. If an assigne assignment. and STATE OR CO | DUNT | | | |
| 4a. The following fee(s) | | | o. Payment of Fee(s): (Plea | on first recombs on | | landu naid icona foa | chown abo | |
| Issue Fee | are submitted. | *** | A check is enclosed. | se msi reappiy ang | prev | lously paid issue fee | snown abo | ve) |
| | vo small entity discount p | ermitted) | Payment by credit car | d. Form PTO-2038 | is atta | ched. | | |
| Advance Order - | # of Copies | | The Director is hereby overpayment, to Depo | authorized to charg sit Account Number | e the r | equired fee(s), any de (enclose a | ficiency, or n extra copy | credit any y of this form). |
| 5. Change in Entity Sta | tus (from status indicate is SMALL ENTITY statu | | ☐ b. Applicant is no lon | ger claiming SMAL | LENT | TITY status. Sec 37 Cl | FR 1.27(g)(| (2). |
| NOTE: The Issue Fee an interest as shown by the | d Publication Fee (if req records of the United Sta | ired) will not be accepte tes Patent and Trademark | d from anyone other than t Office. | he applicant; a regis | tered a | ttorney or agent; or th | e assignee | or other party in |
| Authorized Signature | | | | | | | | |
| Typed or printed nam | e | | | Registration No | э | | | |
| This collection of inform an application. Confiden submitting the complete this form and/or suggests Box 1450, Alexandria, V Alexandria, Virginia 223 | nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC k13-1450. | FR 1.311. The informatis U.S.C. 122 and 37 CFR USPTO. Time will vary den, should be sent to the ONOT SEND FEES OR | on is required to obtain or r 1.14. This collection is est depending upon the indiv e Chief Information Office COMPLETED FORMS TO | etain a benefit by th imated to take 12 m idual case. Any cor r, U.S. Patent and T D'THIS ADDRESS. | e publ inutes nment fraden SENI | ic which is to file (and to complete, includir s on the amount of tin ark Office, U.S. Dep O TO: Commissioner | by the US g gathering ne you requ artment of of for Patents, | PTO to process) g, preparing, and uire to complete Commerce, P.O. P.O. Box 1450, |

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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

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| APPLICATION NO. | FII | FILING DATE FIRST NAMED INVENTOR | | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
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| 10/809,831 | c | 3/26/2004 | Thomas R. Kozel | 031673-003000 | 7955 | | |
| 22204 | 7590 | 09/09/2009 | | EXAMINER | | | |
| NIXON PEABODY, LLP | | | | SWARTZ, RODNEY P | | | |
| 401 9TH STREET, NW | | | | ART UNIT | PAPER NUMBER | | |
| SUITE 900 WASHINGTON, DC 20004-2128 | | | | 1645 DATE MAILED: 09/09/200 | 9 | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/809 831 KOZEL ET AL. Notice of Allowability Examiner Art Unit Rodney P. Swartz, Ph.D. 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 8 June 2009. The allowed claim(s) is/are 15-19,40-49 and 51-60 renumbered 1-25 respectively. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. Examiner's Amendment/Comment Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit 8. T Examiner's Statement of Reasons for Allowance of Biological Material □ Other .

/Rodney P. Swartz, Ph.D./ Primary Examiner, Art Unit 1645 Application/Control Number: 10/809,831 Page 2

Art Unit: 1645

DETAILED ACTION

Applicants' Response to Final Office Action, received 8 June 2009, is acknowledged.
 Claims 15, 16, 19, 40, 43, 44 and 51 have been amended. Claims 33, 35, 36, 37 and 39 have been cancelled.

2. Claims 15-19, 40-49 and 51-60 are pending and under consideration.

Rejections Moot or Withdrawn

- 3. The rejection of claims 33, 35-37 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for discrimination between infected and non-infected subjects, is moot in light of the cancellation of the claims.
- 4. The rejection of claims 15-19, 40-49, and 51-60 under 35 U.S.C. 112, second paragraph, as being indefinite for discrimination between infected and non-infected subjects, is withdrawn in light of the amendments of the claims.

Conclusion

- Claims 15-19, 40-49 and 51-60 are allowed.
- 6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Application/Control Number: 10/809,831 Page 3

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./
Primary Examiner, Art Unit 1645
September 9, 2009